

REMARKS

Claims 1-75 are pending in the present application. Applicants have canceled claims 13-17, 29-33, 44-48, 53-56, 61-64 and 69-72 without prejudice and amended claims 1, 2, 4-12, 18, 19, 21-28, 34-43, 49-52, 57-60, 65-68 and 73. Supports for the amendments to claims 1, 2, 4-12, 18, 19, 21-28, 34-43, 49-52, 57-60, 65-68 and 73 can be found, *inter alia*, in the original claims 1-75 and does not raise any new issue. Therefore, entry of the present Amendment is respectfully requested. Upon entry of the present Preliminary Amendment, claims 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75 will be under examination.

REJECTION OF CLAIMS UNDER 35 U.S.C. 103

Claims 1-75 stand rejected under 35 U.S.C. 103(a) as allegedly being obvious over Myers et al., U.S. Patent No. 5,891,845 ("Myers"), in view of the combination of Benet et al., U.S. Patent No. 6,004,927 ("Benet") and Curatolo et al., U.S. Patent No. 5,605,889 ("Curatolo").

In response, without conceding to the correctness of the Office Action's position, applicants have canceled claims 13-17, 29-33, 44-48, 53-56, 61-64 and 69-72 without prejudice and amended claims 1, 2, 4-12, 18, 19, 21-28, 34-43, 49-52, 57-60, 65-68 and 73 to emphasize that the method and composition comprises azithromycin and nelfinavir or a block copolymer of poly(propylene oxide) and poly(ethylene oxide).

Applicants respectfully point out that the Office Action fails to establish a *prime facie* case of obviousness under the standard of M.P.E.P. § 2142 which states that:

to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the

reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

The Office Action does not meet at least the first and third requirements. Applicants respectfully point out that Myers does not provide any specific teaching, suggestion or motivation to a skilled artisan on how to obtain the claimed method or composition comprising azithromycin and nelfinavir or a block copolymer of poly(propylene oxide) and poly(ethylene oxide). Benet and Curatolo do not remedy the deficiency of Myers.

Moreover, without looking at the disclosure of the present application, one of ordinary skill in the art would not know from Myers, Benet and Curatolo how to obtain the claimed methods and composition comprising azithromycin and nelfinavir or a block copolymer of poly(propylene oxide) and poly(ethylene oxide). Therefore, the Office Action does not satisfy the first criteria for establishing a *prime facie* case of obviousness under M.P.E.P. § 2143.01 because the "suggestion or motivation" criteria must be satisfied from the disclosure of the prior art reference or from the knowledge of persons skilled in the art, not by the use of hindsight in view of the present application (emphasis added).

In this case, even assuming that Myers, Benet and Curatolo can be combined, the combination does not disclose "all the claim limitations." Specifically, the combination of Myers, Benet and Curatolo does not teach or suggest method of increasing bioavailability of azithromycin by the comprising co-administering, to a mammal in need of such treatment, a combination of azithromycin and nelfinavir or a block co-polymer of poly poly(propylene oxide) and poly(ethylene oxide). Applicants respectfully contend that the Office Action fails to satisfy the third criteria for establishing a *prime facie* case of obviousness under the M.P.E.P. § 2143.01. Therefore, claims 1-12, 18-28, 34-43, 49-52, 57-60, 65-68 and 73-75, as amended, are nonobvious over the combination of Myers, Benet and Curatolo. Accordingly, reconsideration and withdrawal of the this ground of rejection are respectfully requested.



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Attorney Docket No. PC10805B

CONCLUSION

In view of the claim amendments and the remarks, early and favorable consideration of all pending claims are respectfully requested.

It is believed that no fee is deemed necessary in connection with the filing of the present Amendment. However, if any fees are required, the Commissioner is hereby authorized to charge any such fees to our Deposit Account No. 16-1445.

Date: _____

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Respectfully submitted,

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